

May 21 2021

To: vetmedregs@agriculture.gov.ie

CC Melanie.Hall@agriculture.gov.ie; Eva.Gethings@agriculture.gov.ie; sheila.nolan@agriculture.gov.ie;

Submission no. 2

EU Regulation 2019/4 on the manufacture, placing on the market and use of medicated feed

IGFA compound feed manufacturers aim to produce nutritionally balanced feed, meeting the farm animals' nutritional requirements and supporting their performance. This enables us to support safe, efficient and economically viable livestock production.

Key to achieving the above is to ensure that the animal's essential nutrition needs are met in terms of energy, essential amino-acids, trace-elements and minerals. An imbalance in nutrition can adversely affect the animal's performance and in severe cases can have a direct impact on health and welfare. Our nutritionists use their expertise and knowledge of the nutritional value of a large range of feed materials to produce feed that is tailor made for the animal to meet its specific nutritional requirements. The (formulated) feed will also be adapted to the life stage of the animal as, for example, the stages of pre-weaning, post-weaning or post-lactating animals all require specific nutrients. In addition, compound feed manufacturers provide livestock farmers with dietetic feeds for farm animals facing particular stress situations in line with [Regulation \(EU\) 2020/354](#).

The production of medicated feed is a service some IGFA feed manufacturers provide to farmers whose veterinarians determine that a medicated feed is required. Within the IGFA membership, the provision of this service is discussed regularly.

DAFM correspondence on 11 March 2021 outlined a number of areas that will impact the business of manufacturing medicated feed. The Industry position and questions on some of the issues contained in that correspondence are outlined below.

DAFM correspondence - Maximum levels of cross contamination for active substances in non-target feed which will have to be adhered to will be set. These levels will be established based on a scientific risk assessment carried out by the European Food Safety Authority in conjunction with the European Medicines Agency. Until the completion of this work, and the establishment of these levels, national maximum levels of cross-contamination shall apply. The Department will run a trial in line with this, whereby action will be taken on the basis of a detection level of 1% or greater of the active substance present in non-target feed manufactured after a medicated feed.

Industry position: It is not possible for medicated feed mills to operated consistently below the current level of what has been considered acceptable i.e. < 3%. This position reflects that of the EU parliament outlined [here](#). Will non-conformances be generated for levels that are not < 3% and damage an industry when it is noted it is part of a trial until levels are set at EU level?

DAFM correspondence - Prescription Changes

1. A prescription for antimicrobials must be filled within 5 days of being issued by the veterinary practitioner.
2. A prescription for any non-antimicrobial medicine must be filled within 3 weeks of being issued by the veterinary practitioner.
3. The length of treatment shall comply with the summary of product characteristics for the veterinary medicinal product but shall not exceed 1 month, or 2 weeks for antibiotics.
4. Each prescription shall only be used for treatment of animals on one occasion.
5. Prescriptions shall be recognised throughout the EU.
6. Animals must be specifically identified on the prescription.

Industry position:

Item 1: Mills operate a 7-day week. If the script is issued on Monday, can it be filled on Saturday?

Item 3: The length of the treatment is not within the control of the medicated feed mill and mills cannot be held responsible for what the veterinary surgeon prescribes.

Item 4: Mills are not in a position to monitor that animals are only treated on 1 occasion on each prescription there cannot be responsible for what the farmers does.

Item 6: Please can you clarify exactly what is meant by "Animals must be specifically identified"?

DAFM correspondence - Animals can no longer be treated with antibiotics in feed as a preventative measure, except in exceptional circumstances.

Industry position: We support this position. However it must be understood that this is not within the control of the medicated feed mill. We therefore would like assurances that the feed mill will not be held responsible for the implementation of this measure.

DAFM correspondence - Mills must have a safe system to collect and discard unused medicated feed. You need a designated area for the storage of expired, withdrawn or returned medicated feed intended for disposal.

Industry position: This is not acceptable to industry as it creates risk to the manufacture of non-medicated feed and serious biosecurity concerns. It would also not be accepted by any of our international feed safety standards.